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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,124	10/17/2001	Allan Green	26-98A	9503

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John P. White, ESQ
COOPER & DUNHAM LLP
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
MCELWAIN, ELIZABETH F	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 08/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,124	GREEN ET AL.	
	Examiner	Art Unit	
	Elizabeth F. McElwain	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-49* is/are pending in the application.

4a) Of the above claim(s) *44-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/059,769.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/17/02, 3/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed May 5, 2005 has been entered.

Claim 26 is currently amended.

Claims 26-49 are pending.

Election/Restrictions

a. Applicants have amended claim 26 so that the some of the present claims relate to those that were originally filed and were subject to restriction. Claims 26-43 encompass the subject matter of the claims originally filed, which have since been cancelled. Claims 26-43 are not subject to restriction given that no SEQ ID numbers are recited in the present claims, and the claims relate to transgenic plants transformed with a nucleic acid encoding a fatty acid epoxygenase gene and a method of making said plants.

b. However, claims 44-49 are drawn to a processes for producing 12, 13-epoxy-9-octadecenoic acid or 12, 13-epoxy-9, 15-octadecadienoic acid and plants apparently produced by said methods. The subject matter of these claims was not present in the claims originally filed.

c. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case these methods do not require the plants of the elected invention, given that plants producing 12, 13-epoxy-9-octadecenoic acid or 12, 13-epoxy-9, 15-octadecadienoic acid are known and

could be used in the same method; and the plant could be used in a different process, such as for food.

d. These claims are hereby withdrawn as drawn to a non-elected invention, wherein these claims would have been restricted, if they had been presented in the originally filed claims.

Specification

2. The disclosure is objected to because of the following informalities: The first paragraph of the specification must be amended to reflect the current status of the parent application, which has issued as a patent.

Appropriate correction is required.

Information Disclosure Statement

The Information Disclosure Statements filed April 17, 2002 and March 19, 2004 have been considered.

Claim Objections

3. Claims 31, 32, 42 and 43 are objected to because of the following informalities: the claims are redundant in that they recite both "flax" and "linseed", which are different names for the same plant. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 26-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to transgenic plants and seeds transformed with a nucleic acid encoding a plant fatty acid epoxygenase and a process for making said plants. However, the specification only exemplifies SEQ ID NO: 1 encoding SEQ ID NO: 2, which have delta-12 epoxygenase activity. The specification discloses other sequences, yet there is no evidence with regard to the functional activity of the other sequences. In addition, the specification (at pages 9-10) states that the invention encompasses any delta-6, delta-9, delta-12 and delta-15 epoxygenase. While, the specification points to the motifs set forth in SEQ ID NO: 15-18, there is no showing that any or all of these motifs define a polypeptide having epoxygenase activity. The specification does not describe structural features that are required for the claimed functional activity, and only one species has been disclosed, which is not sufficient to define the genus. In addition, the state of the prior art does not identify structural features required for epoxygenase activity.

"A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." In addition, "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention". See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

Given the lack of written description for nucleic acids encoding epoxygenases, plants transformed therewith and a process of making said plants. Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

6. Claims 26-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transgenic Arabidopsis and linseed plants that are transformed with a nucleic acid of SEQ ID NO: 1 or a nucleic acid encoding the delta-12 epoxygenase of SEQ ID NO: 2, does not reasonably provide enablement for any transgenic plant species transformed with a nucleic acid encoding any enzyme having any epoxygenase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to transgenic plants and seeds transformed with a nucleic acid encoding a plant fatty acid epoxygenase and a process for making said plants. However, the specification only exemplifies SEQ ID NO: 1 encoding SEQ ID NO: 2, which have delta-12 epoxygenase activity. The specification discloses other sequences, yet there is no evidence with regard to the functional activity of the other sequences. While, the specification points to the motifs set forth in SEQ ID NO: 15-18, there is no showing that any or all of these motifs define a polypeptide having epoxygenase activity.

As Applicants have stated in the specification at page 8, the invention includes any nucleic encoding an epoxygenase from highly divergent species including: bacteria, yeast,

insects, reptiles, birds, amphibians, plants, fungi, molds and algae, for example. In addition, at pages 9-10 of the specification it states that a fatty acid epoxygenase is not limited to one enzyme, but refers to a whole family of enzymes that are involved in the biosynthesis of an epoxy fatty acid, and encompassing any delta-6, delta-9, delta-12 and delta-15 epoxygenase. Not only are there a wide range of epoxygenase activities in this family of genes, but an enzyme that is specific for delta-12 epoxygenase activity can convert a large number of different fatty acids to epoxy fatty acids, including being part of a mixed-function monooxygenase that also has other activities, such as desaturase or hydroxylase activities (see pages 13-15 of the specification).

Van de Loo (in IDS) teach that sequences encoding hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). Thus, if sequences are identified only by similarity to other sequences that are known to encode epoxygenase activity, one cannot conclude on this basis alone that these sequences also will encode a protein having epoxygenase activity. In addition, the specification states that epoxygenase enzymes also share a high degree of sequence homology to desaturase, hydroxylase and acetylenase enzymes (see pages 47-48), and they also share biochemical characteristics (pages 54-55).

The specification only teaches definitive characterization of genes as encoding epoxygenases by transforming the genes into Arabidopsis and analyzing the transgenic plants for production of vernolic acid, which is not otherwise produced in Arabidopsis. The specification provides evidence that one gene isolated from Crepis, which is set forth in SEQ ID NO: 1, was effective in causing the production of vernolic acid in Arabidopsis (page 48). This assay via

transgenic Arabidopsis is the only means that the specification sets forth to determine with certainty that an isolated gene encodes an enzyme having epoxygenase activity.

The specification also teaches several other sequences that are related and were isolated from Crepis, Vernonia, and Euphorbia. The specification teaches that these sequences are more similar to SEQ ID NO: 1 that was shown to have delta-12 epoxygenase activity than they are to related sequences that exhibit desaturase activity. However, the specification does not provide any definitive evidence that these sequences encode enzymes having epoxygenase activity. No other genes from any plant species have been shown to exhibit epoxygenase activity, and the specification does not definitively set forth any specific structural or physical characteristics that would define an enzyme as an epoxygenase. Note that Lee et al (Science 280: 915-918, 1998, in IDS) teach that only moderate changes in amino acid sequence determines whether a polypeptide has acetylenase or epoxygenase activity (the paragraph bridging columns 2 and 3, on page 917).

No epoxygenase genes have been isolated from any other plant species, much less from any other taxonomic kingdom, with the exception of mammalian species. The specification discloses that are about 40% similar to SEQ ID nO: 1. Given the high degree of sequence similarity of genes that encode enzymes that do not exhibit epoxygenase activity, as stated above, the identification of genes encoding fatty acid epoxygenases from other plant species, much less from species from other kingdoms is highly unpredictable, and the existence of other genes from other species and kingdoms other than mammals has not been disclosed. Furthermore, given the low percentage of sequence homology of the mammalian genes to the disclosed plant sequence, the success of the screening method of genes by transformation into Arabidopsis is called into question. So that even if one were to isolate genes from other species

having sequence similarity to SEQ ID nO: 1, it is unclear that one skilled in the art would be able to obtain positive proof that the gene encodes an enzyme that has fatty acid epoxygenase activity. Furthermore, applicants have claimed use of genes encoding any type of fatty acid epoxygenase, but have only provided a screening method for a delta-12 fatty acid epoxygenase.

Therefore, given the unpredictability of identifying sequences that exhibit fatty acid epoxygenase activity; the lack of guidance in the specification for identifying and characterizing any other sequences that exhibit fatty acid epoxygenase activity; the lack of working examples other than SEQ ID NO: 1 in Arabidopsis or linseed; and the breadth of the claims, which encompass all isolated nucleic acid molecules that encode enzymes having any type of fatty acid epoxygenase activity; it would require undue experimentation by one skilled in the art to make and use the invention, as broadly claimed.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth F. McElwain, Ph.D.
Primary Examiner
Art Unit 1638

EFM